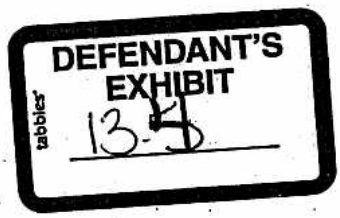
TAP Pharmaceuticals Inc.



January 16, 1995

Confidential

To: Yasu Hasegawa
Don Patton
Will Hall
Doug Durand
George Schaffer

From: Alan MacKenzie

cc: Karen Howard
Rich Daly
Joe Luminiello
Gina Borkowski

Re: **TAP Response to HCFA Initiative - January 6th Meeting with Hogan & Hartson**

I would like to provide a summary of my meeting with Ann Vickery and Donna Boswell, health care attorneys with the Washington law firm of Hogan & Hartson. Ann Vickery in particular has come highly recommended to us from various sources, as an extremely well regarded counsel in the area of Medicare payment policy.

Background

TAP is exploring the use of outside representation to address the HCFA initiative reviewing the use and coverage policy of LHRH agonist. We first learned of this initiative in early December when we received a copy of the attached letter from HCFA to the AUA, which was routed to us from Dolly Hanrahan of Abbott's Washington office. Dolly obtained it from a lobbying contact of hers at the AUA.

TAP's immediate response was to assist the AUA in their response to HCFA. TAP put together and abstracted a sizable body of clinical information addressing the dangers of DES and whatever information was available on patient acceptance, or lack of, of bilateral orchiectomy. This packet was funneled back to AUA via their lobbyist, Randy Fenninger. Attached are a copy of a memo from Randy Fenninger to AUA, as well as a copy of my cover letter on the clinical information packet.

From what we can gather thus far, AUA is not looking for or seemingly desirous of TAP's assistance. The response to our packet to them was, "we'll keep it on file". In parallel to trying to assist and affect the AUA response to HCFA, we also looked immediately at identifying outside counsel to guide us further in formulating a TAP strategy addressing the HCFA initiative. Ann Vickery's name surfaced, primarily because of her work for Amgen in representing them in their numerous difficulties with HCFA over payment policy for Erythropoeitin (Epogen), the single largest drug expenditure into the Medicare part B system. Ann Vickery and others in her group also have extensive experience with Brystol Myers Squibb, representing them on HCFA payment policy for contrast media, also high HCFA expenditures billed into part B. Ann Vickery and her group are also well known to the Abbott Washington office, David Landsidle and Dolly Hanrahan, as a definitive expert in the area of HCFA payment policy.

Summary of January 6 Meeting

Present were Donna Boswell, Dolly Hanrahan, Ann Vickery, and myself. After a review of the entire Lupron line, our markets, our history, competition and our current situation with regard to HCFA, Ann and Donna provided these initial impressions:

- It is questionable if HCFA has the legal authority to engage in this review of Lupron and ultimately the authority to exclude payment. Hogan & Hartson (H & H) recommend a thorough analysis of all applicable laws and would render a legal opinion on that lack of authority.

- H & H would recommend how TAP should apply this legal opinion toward AUA, patient support groups, Medical Directors of State Medicare offices and ultimately HCFA.

- H & H believe that HCFA's motive in their letter to AUA is to have AUA set its own cost effectiveness guidelines on the treatment of Advanced Prostate Cancer. It is HCFA's experience that specialty medical associations set guidelines alter utilization patterns. Furthermore, HCFA would then use these AUA guidelines to set payment policy per the recommended treatment protocols.

- H & H will look within its own base of contacts to see if there is someone who can easily get inside information from the AUA on their activities and intentions on this issue. I indicated to H & H that traditionally the AUA has been difficult for us to get close to and their assistance here will be important.

- H & H will recommend that it formulate an adversary campaign for TAP. This information/approach would again be designed to affect opinion of patient support groups, physician groups, State Medicare Medical Directors and HCFA.

- Longer term, H & H sees a rapid acceleration of Medicare delivery into Managed Care under the new GOP legislative leadership. H & H will recommend a long term strategy for TAP toward Quality of Life Issues, to block cost conscious HMOs from excluding or limiting the use of Lupron. H & H has a lot of experience in this area from their work with Amgen and will make specific recommendations on studies, investigators, approaches and target audiences.

Recommendations

I have asked Ann Vickery to provide us with a proposal as soon as possible. As usual, TAP will clear it with the parents on retaining outside counsel. I recommend that TAP retain Hogan & Hartson to guide and represent us on this issue.

Attachments

TO: Stephanie Mensh

FROM: Randy Fenninger

DATE: December 8, 1994

SUBJECT: Lupron

Today I spoke to Dolly Hanrahan, a lobbyist for Abbott Laboratory which manufactures Lupron through its TAP Pharmaceuticals division, about the HCFA review of Lupron coverage and reimbursement. She suggested that Abbott has some information that may be helpful to AUA in responding to HCFA inquires on this product. I think it makes sense for Dolly and you to discuss AUA's response and information that Abbott has on clinical studies and the like.

My read of the situation at this point is that HCFA will retain coverage for Loupron, but reduce reimbursement. Obviously there is a commercial impact for Abbott, but there is also the impact on AUA members who may lose practice revenue as a result of that decline. This suggest that we seek a way of working with industry and HCFA to address the problem in a sensible way.

Dolly's number here in Washington is 202-659-8524. Please let me know how you would like to proceed with further discussions on this matter.

cc: Dolly Hanrahan

December 20, 1994

Dolly A Hanrahan
Director, Federal Health Policy
Abbott Labs
1710 Rhode Island Ave., N.W.
Suite 300
Washington, D.C. 20036

RE: Support information on the use of LHRH (leutenizing hormone releasing hormone) agonist vs. surgical castration and DES (estrogen) for the treatment of prostate cancer (PCa).

Dear Dolly:

As we discussed, enclosed is the backup data to provide to the AUA in assisting their response. Don Patton (V.P., Marketing) and I would like to meet with you and Ann Vickery to discuss this further. We are assuming that Ann will be put on retainer to TAP, as you suggested.

This is extremely high priority for us and we would like to meet ASAP. We are available to come to D.C. anytime next week.

I'll call you this morning to discuss. Thank you in advance for your help.

Sincerely,

Alan MacKenzie
Director, Sales Operations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administratio

Refer to FEA1

6325 Security Boulevard
Baltimore, MD 21207

[redacted]

Thank you for your recent call in response to my request for the AUA policy on hormonal therapy for prostate cancer. My call was prompted by the extraordinary growth in Medicare expenditures for 2 LHRH agonist analogues: leuprolide acetate and goserelin acetate implant. I greatly appreciate your willingness to discuss this issue with me and to share this letter with the Board of the AUA at your next scheduled meeting.

Following are 4 years of data on Medicare payments to physicians under alpha-numeric HCPCS codes J9217 and J9202. The data reflect the costs of the drugs only. They do not include payments for the administration of the drug or any associated office visits. The definition for J9217 is "Leuprolide acetate (for depot suspension), 7.5 mg" and the definition for J9202 is "Goserelin acetate implant, per 3.6 mg."

Year	J9217 Allowed Charges	J9202 Allowed Charges	Total Allowed Charges
1990	$25,037,963	$560,980	$25,598,943
1991	$107,393,848	$11,543,391	$118,937,239
1992	$185,249,251	$24,613,285	$209,862,536
1993	$294,608,948	$34,085,717	$328,694,665

As I understand it, there are three main therapeutic options available to patients with advanced prostate cancer who are candidates for hormonal therapy. The first is surgical removal of the testicles (orchiectomy) which can be performed safely under local anesthesia on an outpatient basis. There are one time costs associated with the procedure which permanently removes the main source of testosterone. In an ambulatory surgical center, we currently pay a facility fee of approximately $450. The surgeon's payment under the Medicare Fee Schedule is approximately $400.

The second option is oral diethylstilbestrol and aspirin. Because these drugs are self-administered, they are not covered by Medicare. The cost to the patient is about $7/month.

The third option is one of the LHRH agonist analogues. The cost of a monthly injection is approximately $400. Presumably monthly injections continue for the remainder of the patient's life. Frequently added to this therapy is oral flutamide which can cost the patient approximately $200/ month. An alternative to the monthly injections, which could be considered a fourth option, is daily subcutaneous injections which are self-administered and therefore not covered by Medicare.

We are concerned that the extraordinary costs of the monthly injections of LHRH agonist analogues to the Medicare program and to individual patients might not be justified in light of three alternative therapies that may be equally effective but far less costly.

Before we consider any changes in Medicare policy, we would appreciate your thoughts and advice. In particular, we would appreciate a summary of the medical literature regarding the clinical indications, safety and effectiveness of the various options including orchiectomy, diethylstilbestrol and aspirin, monthly injections of an LHRH agonist analogue and daily subcutaneous injections of an LHRH agonist analogue. In addition, information regarding the risks and types of complications associated with the various options would be helpful. Finally, we would appreciate any insights as to why so many physicians and their patients seem to be selecting monthly injections as the treatment of choice.

Thank you for your assistance. I look forward to hearing from you in the near future. If you have any questions, please call me at (410) 966-4492.

Sincerely,

Barton C. McCann, MD

Barton C. McCann, M.D.
Executive Medical Officer
Office of Payment Policy